RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy Research

Volume 1, Number 2 *humanresearch@us.med.navy.mil* *April 3, 2006*

Comment

What is Human Research?

A young Marine leaps onto the beach from a brand-new USMC Expeditionary Fighting Vehicle during a fleet battle experiment. He's wearing a prototype multi-channel radio in a backpack configuration that's being tested for battery endurance, range, security, and frequency-hopping effectiveness.

The experiment also provides the Corps and the contractor a chance to get feedback from Marines assigned to operate the unit on ease of use, wear, portability, and safety of the battery pack—all questions that presumably already would have been addressed in a controlled laboratory environment, but that also require investigation in the field.

Question: Is this human subject research?

The "Common Rule" defines research as "any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." DoD and 16 federal agencies including Health and Human Services, Veterans Affairs, National Science Foundation, and NASA use the same definition.

The Navy's newest instruction on its human research protection program, SECNAVINST 3900.39D, now awaiting signature by the Under Secretary of the Navy, addresses human subject research "conducted in the development, testing, or evaluation of any item, system, vehicle, aircraft, piece of equipment, or other materiel, *even if a person is not the direct object of the research*."

"Delta" expands on the still-current "Charlie" version of 3900.39, and includes "any project, task, test, pilot study, experiment, investigation, study, clinical study, evaluation, developmental effort, or similar undertaking.

What is a "human subject?" The new instruction uses the Common Rule definition: "a living individual about whom an investigator (whether professional or student) conducting research obtains either data through intervention or interaction with the individual or identifiable private information."

"Delta" spells out precisely the meaning of intervention, interaction, and private information from the federal regulations. "Charlie," signed in 2002, did not.

Fleet exercises and fleet battle experiments routinely evaluate prototypes of weapon systems and equipment that personnel will use. Is that research with human subjects? Investigators, acquisition managers, program managers, and command leaders may have differing opinions.

The Navy's Human Research Protection Program is ready to help work through the complexities.

The bottom line: if you're doing a systematic investigation looking for new knowledge, you're doing research. If human beings are in the mix, you may be conducting research with human subjects.

Not sure? Call us.

Also in this Issue of RPU

Decompression Study Planned

Canadians Win Approval to Conduct U.S. Navy Research

In late March, Navy Surgeon General Vice Admiral Donald Arthur approved a Department of the Navy Addendum to a Federalwide Assurance held by Canada's defense research agency, Defence Research and Development Canada (DRDC), permitting the agency to proceed with a study, to be funded by the Office of Naval Research (ONR), of potential ways of mitigating decompression sickness – the "bends."

Captain Chip Auker, Program Officer for Undersea Medicine in ONR's Warfighter Performance Department, says that the proposed study will examine a possible correlation between the acclimation of the human body to heat and the biochemical effects of decompression on divers.

He says that the effort, designated "Neuroendocrine and Immunological Response to Acute Hyperbaric Stress Before and After Heat Acclimation," will look at "non-recompressive" ways of helping divers recover from dives that today require either a gradual ascent or recovery in a recompression chamber.

Auker explains that if a diver ascends too quickly, nitrogen bubbles form in his bloodstream, resulting in a biochemical reaction that causes decompression sickness, or DCS, which, if not treated immediately, can cause severe injury or death.

The Naval Medical Research Center (NMRC), in research using rats, has determined that multiple exposures to compression and decompression produce resistance to decompression sickness through a physiological process termed "acclimation." DRDC has proposed studies, using human divers, that will determine if multiple exposures to a heat stress will similarly produce resistance to decompression

Captain Auker

sickness through a process called "cross-acclimation." DRDC, which holds a Federalwide Assurance, has conducted other research for ONR. The FWA, however, does not require compliance with Department of Defense and Navy requirements.

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The DoD-Navy Addendum to the FWA requires institutions to comply with DoD and DON policies for human subjects*. The Addendum highlights key policy requirements such as: initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research; written determination by a designated official (other than investigators) whether research meets criteria for exemption.*

The Addendum also points out: new research and substantive amendments to approved research must undergo scientific approval prior to ethics (IRB) review; additional protections for military research subjects to minimize undue influence; compensation for U.S. military personnel; provisions for research-related injury; and appointment of medical monitors. The Addendum emphasizes policy limitations on research where consent by legally authorized representatives is proposed and on exceptions from informed consent in emergency research.

The Addendum stipulates that U. S. Navy-wide survey research requires additional review; the prohibition of research with prisoners of war and detainees; provisions for research with human subjects using investigational test articles (drugs, devices, and biologics); and the DON HRPP oversees research with human subjects.

RPU Interview

ONR's Deniston: Education A "Critical Challenge"

LCDR William Deniston, a native of Carbondale, Ill., was commissioned in December 1996 and earned his Ph.D. in experimental psychology in 1997. He joined the Naval Health Research Center and in 2000 was assigned as program manager in NHRC's Field Medical Technologies department, the first lieutenant to serve in that role. He then served at Space and Naval Warfare Systems Center as co-lead for command performance improvement. He reported to Office of Naval Research (ONR) in October 2004, where he served initially as deputy director of the Neural, Cognitive, and Social S&T Division. In September 2005 he was named deputy director of ONR's new Research Protections Division. William and his wife Leah have two sons, Philip and Jake.

Tell us about ONR's role in the Human Research Protection Program.

The Under Secretary of the Navy's Executive Decision Memorandum of April 29, 2005 assigned the Surgeon General as single point of accountability for human subject research. Subsequently the SG delegated to Chief of Naval Research responsibility for oversight and monitoring of compliance with human research policy by operational fleet and training commands, the Navy's Systems Commands, and "extramural" organizations—the universities and industry labs that conduct research for the Navy. ONR has established a new Research Protections Division, ONR 343, for which I serve as deputy.

What organizations among ONR's "clients" conduct research with human subjects?

We know that many fleet commands do so, for example, in the context of fleet battle experiments and other testing environments. Other activities at training commands and within the SYSCOMs also conduct research. In November our team visited the Navy Experimental Diving Unit, which was described in last month's newsletter.

What do you see as the challenges facing ONR 343?

A critical challenge is education—we're working to get research personnel through our training programs. We hope to have a Navy training site up within the next couple of months. Another aspect of the educational challenge is ensuring that the unit leaders in the operational fleet, at the training commands, and at the SYSCOMs know that certain activities, including some that may have been going on for years, are in fact research. The new Navy instruction on human research protection, SECNAVINST 3900.39D, awaiting signature, spells out what research encompasses.

Leah, Philip, Jake and William

Some people don't realize they're doing human research. They need to know that they have an obligation to protect human subjects, not only because it's the law, but also because it's good leadership. As we increase awareness in the research activities, we stress that we're not trying to make their lives more complicated—we want to help them comply with the law so they can carry out their missions.

What response have you had thus far?

It's been very favorable. I mentioned our visit to NEDU—everyone was very positive. We've also worked with other commands, answering their questions, which have been good ones. People want to do the right thing.

What's the Division's strategy at this point?

Our goal is to serve as a positive resource for Navy commands that do research, helping them comply with Navy policy on protecting human subjects. We want to help them avoid doing something wrong where human subjects are concerned, that could jeopardize their ability to perform their missions—whether those missions are fleet operations, training, or developing technologies needed by Navy operators. We're not in business to shut research down—we want to help the commands comply with policy and keep doing their jobs.

HRPP Questions and Answers

Spotlight on Assurances

My command is completing the application for an Assurance to conduct research with human subjects. We don't have our own IRB and will rely on another command's IRB for review. Who signs where?

After completing the training, the CO signs the Assurance for the command in the section marked "Institutional Signatory Official for the Institution Providing this Assurance" (Part 3). Your Primary Contact for the Command's HRPP also signs Part 3. The CO and the IRB Chair(s) of the command with the reviewing IRB sign the sections marked "Institutional Signatory Official of the Institution with the Reviewing IRB" and "IRB Chair(s) of the Institution with the Reviewing IRB" in Part 2.

If our command is relying on another command's IRB for review, how should we complete Part 4 of the Assurance, Summary of Institution's Supporting Information?

You may reference the policies and procedures for the command whose IRB is providing the review, where applicable, as part of your assurance. Please refer to application directions and the self-assessment checklist for details. Your command remains responsible for monitoring and overseeing the research being conducted at your command and must define its own policies and procedures. Contact DON HPPP for a model SOP for Monitoring and Overseeing Human Subject Research.

We have completed a Joint Research Review Agreement and an Assurance Application. Our commanding officer wants to know if he has to sign these or if he can get someone else to sign off "by direction."

Only the CO has the authority to assume the responsibility for the institution's commitments outlined in the Assurance. Likewise, only the CO has the authority to assume responsibility for agreements between institutions on human research protections. This authority cannot be delegated to individuals who don't have the administrative or legal authority to enforce human research protections and the terms of the agreement.

The new directions for completing the DON HRPP Assurance application explain that the Institutional Signatory Official must be a senior official authorized to represent the institution, and any other institutions named in the Assurance, and to assume on behalf of the institution the obligations imposed by federal regulations, DoD, and DON requirements for protection of human subjects. In most cases, the Commander, Commanding Officer, Officer-in-Charge, or Head of Activities serves as the Institutional Signatory Official.

(Continued from page 2) **Canadian Research**

The Navy's Human Research Protection Program, spelled out in a new instruction (SECNAVINST 3900.39D), now awaiting signature by the Under Secretary of the Navy, stipulates that institutions, even those holding FWAs, that seek to conduct research with human subjects provide written assurance in the form of the Addendum that they will comply with DoD-Navy requirements.

The DRDC submitted its signed Addendum—the first-ever to be submitted in accordance with the new instruction—in late February. Dr. Tom McLellan, who is overseeing the DRDC work, said that the agency "found the process quite clear and easy to follow."

RESEARCH PROTECTIONS UPDATE *is published monthly by the Department of the Navy Human Research Protection Program. email address: humanresearch@us.med.navy.mil. CAPT Eileen Villasante, publisher, Edward J. Walsh, editor. Telephone: (703) 588-1010; E-mail: walshe@onr.navy.mil. Material appearing in* **RESEARCH PROTECTIONS UPDATE** *is not copyrighted and may be redistributed in electronic or printed form.*